DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. LEDESMA

Food and Drug Administration

[Docket No. 2004N–0026]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Form FDA 3356

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to FDA regulations for establishment registration and listing for human cells, tissues, and cellular and tissue-based products (HCT/Ps) and the associated Form FDA 3356 used to report establishment registration and listing information.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**.]

ADDRESSES: Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration,

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5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through

the use of automated collection techniques, when appropriate, and other forms of information technology.

Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing; Form FDA 3356—21 CFR 1271 (OMB Control Number 0910–0469)—Extension

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. As derivatives of the human body, all HCT/Ps pose some risk of carrying pathogens that could potentially infect recipients or handlers. The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute any HCT/P, or that perform screening or testing of the cell or tissue donor to register with FDA (§ 1271.10(b)(1)) and submit a list of each HCT/P manufactured (§ 1271.10(b)(2)). Section 1271.21(a) requires the initial establishment registration, and section 1271.25(a) and (b) identify the required initial registration and HCT/P listing information. Section 1271.21(b) requires an annual update of the establishment registration. Section 1271.21(c)(ii) requires establishments to submit HCT/P listing updates when an HCT/P is changed as described in section 1271.25(c). Section 1271.25(c) identifies the required HCT/P listing update information. Section 1271.26 requires establishments to submit an amendment if ownership or location of the establishment changes.

FDA requires the use of a registration and listing form (Form FDA 3356; Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps); *http://forms.psc.gov/forms/FDA/fda.html*) (§§ 1271.22 and 1271.25) to submit the required information. To

further facilitate the ease and speed of submissions, electronic submission is accepted (*http://www.fda.gov/cber/tissue/tisreg.htm*).

Sections 207.20, 207.26, 207.30 (approved under OMB control number 0910–0045), and 807.22(a) and (b) (approved under OMB control number 0910–0387) (21 CFR 207.20, 207.26, 207.30, and 807.22(a) and (b)) already require establishments that manufacture drugs or devices to submit to FDA initial establishment registration and product listing, as well as annual establishment registration, product listing updates, and location and ownership amendments. Sections 207.20(f) and 807.20(d) require that manufacturers of HCT/P drugs (subject to review under an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) or under a biological products license application under section 351 of the PHS Act (42 U.S.C. 262)) and devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the act or under a biological product license application under section 351 of the PHS Act) submit this registration and listing information using Form FDA 3356 instead of the multiple forms identified under parts 207 and 807. Therefore these establishments (FDA estimates a total of 67 (1+66) respondents as shown in table 1 of this document) will incur only a one-time burden to transition from the use of several forms to the use of one form.

Respondents to this information collection are establishments that recover, process, store, label, package or distribute any HCT/P, or perform donor screening or testing. In table 2 of this document, based on information from FDA's database system for the fiscal year (FY) 2003, there are 1,003 establishments that have registered and listed with FDA. This number includes 552 establishments manufacturing conventional or ocular HCT/Ps, which are

currently required to register and list with FDA. The remaining 451 establishments are manufacturers of hematopoietic stem cells derived from peripheral or cord blood, and reproductive cells and tissue. Although these establishments currently are not required to register and list, some have registered voluntarily and are therefore included in the burden estimate. Based on information from FDA's database for FY 2002, there were 484 listing updates and 12 location/ownership amendments. When registration and listing requirements are implemented for all HCT/P establishments, i.e., when sections 207.20(f), 807.20(d), and 1271.3(d)(2) are effective, FDA estimates in table 1 of this document that approximately 367 (300+66+1) HCT/P establishments would initially register and list in addition to the 1,003 currently registered establishments.

The burden estimates for the initial registration and listing and average hours per response are based on institutional experience with comparable reporting provisions for drugs including biological products, and devices, information from industry representatives and trade organizations, and data provided by the Eastern Research Group, a consulting firm hired by FDA to prepare an economic analysis of the potential economic impact on sperm banks and other reproductive tissue facilities.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED INITIAL (ONE-TIME) REPORTING BURDEN[1]

21 CFR Section	Form FDA 3356	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
207.20(f)	Change to Form 3356	1	1	1	0.5	0.5
807.20(d)		66	1	66	0.5	33
1271.10(b)(1) and (b)(2), 1271.21(a), and 1271.25(a) and (b)	Initial registration and listing	300	1	300	0.75	225
Total						258.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Form FDA 3356	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1271.10(b)(1) and 1271.21(b)	Annual Registration	1,003	1	1,003	0.5	501.5
1271.10(b)(2), 1271.21(c)(ii), and 1271.25(c)	Listing Update	484	1	484	0.5	242
1271.26	Registration Amendment	12	1	12	0.25	3
Total						746.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 1-21-04
January 21, 2004.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

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